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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/628,309 | 07/29/2003 | Benjamin Pelcman | 7567/80568 | 4464 |
| 22242 | 7590 | 09/17/2004 | EXAMINER | |
| FITCH EVEN TABIN AND FLANNERY 120 SOUTH LA SALLE STREET SUITE 1600 CHICAGO, IL 60603-3406 | | | HUANG, EVELYN MEI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,309

Applicant(s)

PELCMAN ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-100 is/are pending in the application.
- 4a) Of the above claim(s) 61,62,98 and 99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-60,63-97 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/029,468.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 25-100 are pending. Claims 1-24 have been canceled according to the amendment filed on 8-5-2004.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 25-60, 63-97, 100, drawn to a compound of formula (I), its composition, process of making and the method for treating pain.

Group II, claim(s) 61, 98, drawn to an alternative method for treating a gastrointestinal disorder.

Group III, claim(s) 62, 99, drawn to an alternative method for treating spinal injury.

Under PCT Rule 1.31 and 13.2 and 37 CFR 1.475, an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to one of the following combinations of categories:

- a. A product and a process especially adapted for the manufacture of the said product; or
- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product, and a use of the said product.

This application contains claims to more or less than one of the combinations of categories of invention set forth above since it contains 2 additional alternative processes of use as described in Group II and Group III inventions.

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3. During a telephone conversation with Mr. Sanzo on 9-8-2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 25-60, 63-97, 100. Affirmation of this election must be made by applicant in replying to this Office action. Claims 61, 62, 98, 99 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 36, 44, 47, 52, 65, 66, 74, 79, 82, 85, 90, 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Since claim 36 is dependent on claim 35, the reference to claim 25 is confusing. It is recommended that 'and R6, R7, Z1 and Z2 are as defined in claim 25' be deleted to better define the claim.

b. Since claim 44 is dependent on claim 43, the reference to claim 25 is confusing. It is recommended that 'wherein R4 and R5 are each and independently as defined in claim 25' be deleted to better define the claim.

c. Since claim 47 is dependent on claim 43, the reference to claim 25 is confusing. It is recommended that 'and R6, R7, Z1 and Z2 are as defined in claim 25' be deleted to better define the claim.

d. Since claim 52 is dependent on claim 46, the reference to claim 25 is confusing. It is recommended that 'and R6, R7, Z1 and Z2 are as defined in claim 25' be deleted to better define the claim.

e. Claims 65, 66, 79, 82, 85, 90 are dependent on the base claim 63, the reference to claim 25 have no antecedent basis in the base claim 63.

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f. Since claim 75 is dependent on claim 73, the reference to claim 63 is confusing. It is recommended that 'and R6, R7, Z1 and Z2 are as defined in claim 63' be deleted to better define the claim.

g. Claim 100,

- The claim as presented would only allow the making of the compound of claim 25 and not the compound of claim 63, since all the variables of the reactants are as defined in claim 25. It is recommended that the process of making the compound of claim 25 and the process of making the compound of claim 63 be presented in separate claims with the corresponding reactants.
- Step (b) and (d), 'optionally modifying R1' is open-ended and would embrace modifying R1 to any substituents not recited in the claim or described in the specification.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-60, 63-97, 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20, 24, 27, 28 of U.S.

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Patent No. 6153626. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The compound of instant claim 57 is identical to the first compound of claim 4 in the patent. The species compounds of claim 4, the composition, the process of making, and method of use thereof, are encompassed by the instant claims 25-56, 58-60, 63-97, 100. The instant compound, the composition, the process of making and method of use thereof, are encompassed by the patented claims 1-3, 5-20, 24, 27, 28.

Conclusion

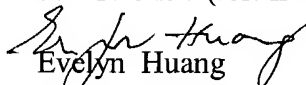
6. Claims 25-60, 63-97, 100 would be allowable upon overcoming the 112 second paragraph rejection and the obviousness type double patenting rejection.

Carson (6436959, PTO1449), having a filing date of 12-23-1998, is not available as prior art under 102(e). Furthermore, the substituents on the phenyl of phenylC₂₋₄alkyl of Carson's R6 are different from the substituents on the aryl of C₁₋₂alkylaryl of instant R1.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625